UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Support Document #31

AUG 25 1993

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Implementation Paper for the New Paradigm

FROM: Douglas D. Campt
Office Director
Office of Pesticide Programs (H7501C)

TO: Victor J. Kimm
Acting Assistant Administrator

As you know, the policy decisions of the Ecological Effects and Environmental Fate Task Force were published in October 1992. The Office of Pesticide Programs formed a Workgroup in response to these policy decisions, which was charged with developing a plan to implement these decisions.

As agreed upon our briefing of July 28, we have completed our paper that describes the implementation plan and are forwarding it to you. The plan has been written to provide people both inside and outside the Agency with a conceptual outline of the process. Detailed implementation steps have purposefully not been included to allow the process to remain dynamic and evolve over the course of the next year.

We have had a great deal of interest in the implementation plan and are eager to distribute this document to people both within and outside the Agency. As soon as we receive your approval, we will begin this process.

If you have any questions, feel free to call me.

Attachment

Implementation of the Policy Decisions of the Ecological Effects and Environmental Fate Task Force

I. Introduction

In March 1992, Linda Fisher, then Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances of the Environmental Protection Agency (EPA), established an Ecological, Fate, and Effects Task Force. The objective of this Task Force was to review and assess the role of ecological and environmental fate data and data requirements on registration[1] and reregistration decision-making.

Specifically, the Task Force focused on how required ecological and environmental fate data are used in the risk assessment and risk management processes and how these data add to registration and reregistration decisions. In addition, the Task Force evaluated the impact of these data requirements on the timeliness of congressionally mandated reregistration deadlines as well as on the registration process.

In October 1992, the policy decisions of the Task Force were published (Ref. 4), and the Implementation Workgroup was formed to develop a plan to implement the "new paradigm". This document describes the implementation plan developed by the Workgroup, which is intended to provide people both inside and outside the Agency with a conceptual outline of the new process. Detailed implementation steps have purposefully not been included to allow the process to remain dynamic and evolve over the course of the next year. More detailed guidance will become available as the process evolves.

This document is organized into six sections. Section II provides background information and summarizes the policy decisions made by the Task Force. Sections III and IV describe the conceptual plan to implement the new paradigm for ecological effects and ground water, respectively. Section V provides clarification and responses to questions that have arisen regarding the new paradigm. The document ends with Section VI, a conclusion, which identifies long-term research goals, and Section VII which provides references.

II. Background

A. Definitions

Three components of the decision-making process under the new paradigm are risk assessment, risk management, and risk mitigation. These components are defined as follows:

---

[1] For the purposes of this paper, registration refers to the registration of new pesticides as well as the addition of new uses to already registered chemicals.

- Risk assessment is the scientific phase of the overall process and consists of hazard identification, and exposure assessment, ultimately integrates hazard and exposure to characterize risk.

- Risk mitigation involves mitigation measures to reduce or eliminate source contamination and adverse environmental impact.

- Risk management is a policy-based activity that defines risk assessment questions and endpoints to protect human health and ecological systems. It takes the scientific risk assessment and incorporates social, economic, political, and legal factors, which impinge or influence the final decision and selects regulatory actions.

B. Task Force policy decisions

Two key policy decisions were (1) an emphasis on risk mitigation early in the data gathering process and (2) less emphasis on field studies. A discussion of these two topics is in sections A and B. The Task Force also proposed specific levels of concern (LOC). These are identified in section C.

In addition, the Task Force encouraged the Office of Pesticide Programs (OPP) to consider more realistic exposure estimates when calculating estimated environmental concentrations (EECs). One recommendation was to see whether actual residue data were available within OPP that could be used to improve exposure estimates. OPP was encouraged to investigate how environmental fate data could be incorporated more effectively into exposure estimates and into the ecological risk assessment process.

The Task Force also indicated that registration and reregistration decisions could be revisited in the future. As a result, the Task Force encouraged OPP to begin development of a long-term strategy for making regulatory decisions regarding pesticide impacts and ecological risk. The strategy should aim to reduce the risk to aquatic ecosystems and should consider developing a regulatory scheme for protecting these systems from the long-term effects of pesticide use. OPP was urged to propose a research plan for improving the understanding of pesticide impacts on birds and to obtain the information needed to reduce the uncertainty in evaluating ecological risk. Finally, OPP was encouraged to consider how risk assessment and risk management could be more clearly defined and more effectively integrated, especially in the area of ecological risk.

1. Early mitigation

The Task Force concluded that risk managers must make decisions regarding ecological risk and ground-water earlier in the data gathering process. Risk managers also should rely heavily on risk mitigation when data indicate that one or more of the LOCs have been exceeded. OPP was directed to use risk mitigation to the extent feasible to improve environmental quality. To ensure that risk mitigation was successful, OPP was encouraged to consider requiring follow-up monitoring studies that would allow the Agency to evaluate the success of the imposed mitigation measures.

For ecological effects, the Task Force also emphasized that EPA "will not accept widespread and repeated mortality in the face of minor economic benefits to society. The 'widespread and repeated' standard can be met on a local or regional as well as national basis" (Ref. 4).

2. Less dependence on field studies

a. Ecological effects

In general, the Task Force concluded that (1) field studies do not provide risk managers with the kind of information that greatly enhances risk management decisions and that (2) regulatory decisions over the course of reregistration would be made in the absence of higher-tiered field studies whenever possible. As a result, OPP will no longer require avian and aquatic field studies (mesocosms), except in unusual circumstances. When field study data are lacking, decisions will be based upon other data sources, such as laboratory studies, published information and incident data. Endpoints of concern include acute and chronic toxicity. The Task Force acknowledged that indirect effects could be important, but that EPA currently does not have a testing scheme in place to accurately measure such effects within the time specified for reregistration. However, the Task Force also emphasized that if a risk manager feels that a regulatory decision cannot be made in the absence of aquatic or avian field studies, the studies can be required.

b. Ground water

The Task Force made several general recommendations with the purpose of increasing OPP's ability to make protective and timely decisions about the impact of pesticide use on ground-water quality. OPP was encouraged to make regulatory decisions where possible without requiring additional field studies, basing these decisions on the quality of existing data, environmental fate characteristics, existing monitoring databases, and modeling. By making these decisions at an earlier stage in the regulatory process, OPP will increase the likelihood that ground-water

quality will not be degraded as a result of continued use of the pesticide. If existing databases do not provide an adequate basis for these regulatory decisions, risk mitigation measures may be imposed prior to the requirement for ground-water studies to confirm the impact on ground-water quality. Also, if it is unclear that the impact of mitigation measures will result in a significant improvement in protection of ground-water resources, monitoring may be required to insure its effectiveness.

C. The LOCs and Other Criteria for Regulatory Action

1. Ecological Effects

Aquatic, acute effects

- If the EEC > 1/2 LC_{50}[2], the acute aquatic risk is of high concern and may warrant regulatory action in addition to restricted use classification.

- If 1/10 $LC_{50} \leq$ EEC $\leq$ 1/2 LC_{50}, then the pesticide is considered for restricted use classification.

- If EEC < 1/10 LC_{50}, then the pesticide has a low acute aquatic risk, and no additional regulatory action is warranted.

- Incidents[5] may also trigger further assessments and will be analyzed on a case-by-base basis.

Aquatic, chronic effects

- If the EEC $\geq$ LEL[3], then the chronic aquatic risk is of high concern and may warrant regulatory action.

Avian acute effects --

- If the EEC > 1/2 LC_{50} or LD_{50}[4]/sq ft > 1/2, the acute avian risk of a pesticide is of high concern and may warrant regulatory action in addition to restricted use classification.

---

[2] The median lethal concentration necessary to effect 50% of the test population.

[3] Lowest effect level.

[4] Median lethal dose necessary to effect 50% of the test population.

- If (1) 1/5 $LC_{50} \leq$ EEC $\leq$ 1/2 LC_{50} or (2) $LD_{50} \leq 50$ L/kg for granular formulations[5], then the pesticide is considered for restricted use classification.

- If (1) EEC < 1/5 LC_{50} or (2) LD_{50}/sq ft < 1/5[5], then the pesticide has low acute avian risk and no additional regulatory action will be pursued.

- Incidents[5] may also trigger further assessments and will be analyzed on a case-by-base basis.

Avian chronic, effects

- If the EEC $\geq$ LEL, then the chronic avian risk is of high concern and may warrant regulatory action.

Endangered species

The criteria that are used to determine if a pesticide may affect listed species are outlined in EPA's Standard Evaluation Procedure for Ecological Risk Assessment (Ref. 3).

2. Ground water

Mobility

- Kd[6] $\leq$ 5 L/kg or Koc[7] $\leq$ 500 L/kg or detection of compound 90 cm in soil profile in soil dissipation study, and

Persistence

- Soil half-life > 2 - 3 weeks, and

Risk based trigger

- The policy regarding the type of regulatory action based on human and ecological end points is still proposed and is subject to further clarification.

Detections[5]

- Detections also will play a role in the weight-of-the evidence evaluation regarding the potential of a pesticide to contaminate ground water. The nature of the detections needed to go from one regulatory action to another will be

---

[5] Not originally identified in the published findings of the Task Force.

[6] Partition coefficient.

[7] Organic carbon partition coefficient.

delineated in the proposed regulations covering restricted use classification and state management plans.

IV. Implementation Plan for Ecological Effects

The Implementation Workgroup began by focusing attention on a conceptual process to implement the Task Force policy decisions related to ecological risk. The process was designed to address two goals.

The first goal was the need to meet Congressionally-mandated deadlines for reregistration. Therefore, the process was designed to be completed in a fairly short timeframe, starting with step 4. OPP anticipates that the process generally will take less than 9 months beginning with step 4. It should be noted, however, that the process initially may take longer since it will be evolving over the course of the next year.

Timeframes have not been provided for steps 1, 2, and 3. These steps are part of OPP's routine scheduling of program activities, which will coordinate the timing of chemicals going through the implementation steps with other program activities, including reregistration.

The second goal was to make decisions that would protect environmental resources. To fulfill this goal, the process emphasizes risk mitigation and implements post-registration and reregistration monitoring as a discrete component of the process to ensure effective risk mitigation measures. The new paradigm will require OPP to identify potential mitigation measures early in the process, which is soon after an LOC exceedence is identified. Registrants are notified of the LOC exceedence and encouraged to propose risk mitigation measures during the negotiations. This results in more timely and potentially more protective decisions.

The process itself is described through a series of implementation steps, which are discussed below.

Step 1 - Define ecological risk assessment, identify endpoints of concern, and prepare preliminary usage information.

The focus of this step is to determine the kind of information and assessments that a risk manager needs to make a regulatory decision for a particular pesticide. This determination includes identifying the endpoints of concern as well as identifying the appropriate risk management questions, which may vary depending on the chemical.

This step is an important one and directly addresses one of the concerns highlighted by the Task Force, which is that the roles of the risk assessors and risk managers are not well

defined or understood in the area of ecological effects. Step 1 is an attempt to address this and to more effectively integrate risk assessment and risk management.

In step 1 the use sites that will be targeted in the risk assessment also will be identified. In addition, BEAD will begin to prepare preliminary usage information on those sites. If a new chemical is being considered for registration, BEAD also will determine the need to require efficacy data.

Step 2 - Schedule preliminary risk assessment.

This is an administrative step during which a schedule is developed for the scientific review of a new pesticide or one undergoing reregistration. Enough time needs to be allocated in the schedule to allow the process to reach completion. The lead division is either SRRD or RD, depending on whether its a new pesticide or one undergoing reregistration. SRRD and RD negotiates with EFED and BEAD when developing the schedule.

Step 3 - Perform initial risk assessment.

Steps 3 and 4 essentially serve as a screen. EFED conducts the initial risk assessment that includes (1) calculating risk quotients and (2) gathering any information related to risk characterization that is readily available. The quotients will be estimated based on Kenaga (Ref. 1) and preliminary aquatic exposure scenarios.

Step 4 - Identify LOC exceedence and notify Lead Division. (Timeframe - 1 week)

Once the quotients have been calculated, they are compared to the LOC. If the LOC is not exceeded, work continues to register/reregister the pesticide. In contrast, if the LOC is exceeded, EFED notifies SRRD, RD, BEAD, and FOD of their concern.

Step 5 - Refine risk assessment and identify potential mitigation measures. (Timeframe - 6 weeks)

Once a concern has been raised by the LOC exceedence, EFED modifies the risk assessment (initial screen) by further evaluating toxicity and modifying the exposure estimates. This may be achieved by considering additional toxicity data as well as available field residue data, actual usage data, as well as utilizing more sophisticated models. Environmental fate data will be incorporated, and additional information related to risk characterization is gathered. The results are once again compared to the LOCs. If the LOCs are not exceeded, work continues to register/reregister the chemical. Depending on the certainty associated with the assessment, field monitoring may be considered.

As mentioned previously, the new paradigm emphasizes risk mitigation for ecological effects when data indicate that an LOC has been exceeded. If the LOC is still exceeded after the risk assessment has been refined, OPP will begin to identify potential mitigation measures and consult with BEAD regarding their potential feasibility.

In the past mesocosms or avian field studies were often required if the LOC was exceeded. As stated previously, the new paradigm generally places less emphasis on field studies. As a result, field studies will only be required if the circumstances are unusual, such as a new mode of action or a new chemical class. If a field study is warranted, EFED will recommend that it be required.

Step 6 - Notify registrant of LOC exceedence. (Timeframe - 3 weeks for steps 6 and 7)

This is a notification step. SRRD or RD notifies the affected registrant that OPP is concerned about the pesticide and that the registrant should consider proposing risk mitigation measures (step 8). Documentation from the refined risk assessment is included in the notification.

Step 7 - Identify cost and applicability of mitigation measures and prepare preliminary benefits assessment.

To prepare for the meeting with the registrant, OPP will evaluate the economic impact of the mitigation measures identified in step 5. To accomplish this, BEAD will develop a preliminary cost analysis of the mitigation measures. BEAD also will begin work on the preliminary benefits assessment, including identification of alternatives. In addition, OPP will develop strategy for negotiation.

Step 8 - Negotiation. (Timeframe - 4 weeks)

As indicated previously, one of the key results of the Task Force was an emphasis on risk mitigation early in the process. Under the new paradigm, SRRD or RD will negotiate with the registrants. The negotiation will consider OPP's concerns about the pesticide and will address potential risk mitigation measures. This is less than one month after the risk assessment has been refined.

In some cases, a public meeting may take place. OPP anticipates, however, that this will not occur routinely. In those cases when a public meeting is held, OPP anticipates that the 9 month timeframe may be exceeded.

In either case, the timeframe for step 9 will be determined during this step.

Step 9 - Evaluate effectiveness of proposal and consider remaining risk with respect to LOC and preliminary benefits and make a regulatory decision. (Timeframe - 4 - 12 weeks)

During step 9, the risk is re-evaluated considering the registrant's risk mitigation proposal or one that is negotiated between OPP and the registrant in step 8. A preliminary risk/benefit assessment is conducted. The tasks that need to be completed during this step include

- Evaluating the registrant or negotiated proposal and effectiveness of mitigation based on the available data,
- Characterizing the risk to the extent possible,
- Evaluating the pesticide alternatives,
- Weighing risks and benefits,
- Deciding whether to accept or reject the proposal, and
- Determining whether to require follow-up data[8] to help answer risk management questions not previously addressed and/or to monitoring the effectiveness of risk mitigation measures.

At the conclusion of this step, a decision should be made whether or not to register/reregister the pesticide based on the preliminary risk/benefit analysis. If additional data are needed, they will be required, and the results used in a later evaluation of the pesticide. These additional data can be required as a condition of registration or a confirmation of reregistration eligibility decisions. Together with changes in the benefits, they will form the analytical basis for achieving continuous improvement when revisiting the decision in the future.

If the decision is made not to register/reregister, then a full risk/benefits assessment will be performed (step 10). OPP anticipates, however, that step 9 will be the final step for most pesticides and that they will not need to continue to step 10.

Step 10 - Perform full risk/benefits assessment.

In those cases where a registration/reregistration decision cannot be made, the risk and benefit assessments that have been conducted up to this point will be expanded. EFED will need to

---

[8] Follow-up data could include aquatic or avian field studies or monitoring studies to address questions on long-term direct and indirect effects on individuals, populations, or ecosystems.

expand the alternatives assessment and fully characterize the risk based on a weight-of-the-evidence analysis, including extent of use, incident reports, species exposed, and quality of habitat. BEAD will also expand their alternatives assessment as well as conduct a full benefits assessment.

Step 11 - Make regulatory decision based on risk/benefit assessment.

Once the expanded risk/benefits assessment has been completed, a regulatory decision will be made. This requires an unreasonable risk determination and evaluating potential regulatory options. These options could include registration/reregistration, requiring additional data, label changes, and potentially cancellation. Once the options have been evaluated, SRRD or RD will make a regulatory decision. If additional data such as monitoring are needed, they will be required.

V. Implementation Plan for Ground Water

Once the plan for ecological risk was completed, the Implementation Workgroup focused their attention on developing a conceptual process to implement the Task Force policy decisions related to ground water. The results are described below. This process beginning with step 3 is also anticipated to take less than 9 months.

Similar to the plan for ecological risk, the process for ground water also was designed to fulfill the two goals -- making more timely reregistration decisions as well as more protective decisions. These goals will be achieved by focusing on risk mitigation early in the process. In the past, risk mitigation was not considered until after ground-water monitoring studies had been submitted. Under the new paradigm, risk mitigation along with potential monitoring requirements will be considered after the potential to contaminate ground water has been evaluated.

It is important to note that the Agency's policy for regulating pesticides that have the potential to contaminate ground water is still evolving. As a consequence, the steps outlined below may change or may not be followed in the same manner for all pesticides.

Step 1 - Schedule preliminary environmental exposure assessment.

This is an administrative step during which SRRD or RD develops a schedule for the science branches to review a new pesticide or a reregistration chemical. The schedule must reflect enough time to allow the process to be completed.

Step 2 - Review and evaluate environmental fate and transport data.

EFED will review and evaluate the environmental fate and transport data for the purpose of developing an environmental exposure assessment. For new pesticides and for reregistration chemicals, this effort includes evaluating laboratory and field dissipation studies. For reregistration chemicals, it also involves a cursory review of the information available in the ground-water data base.

EFED will evaluate the need for further assessment based on the weight-of-the-evidence analysis of environmental fate and transport data. If further assessment is not needed, work continues to register/reregister the pesticide.

Step 3 - Schedule ground-water evaluation and notify SRRD, RD, HED, PSPS, and BEAD. (Timeframe - 2 weeks)

If EFED determines the need for further assessment, EFED confers with other scientists to see if there is any potential ecological or human health impact from ground-water contamination. This includes conferring with the Ecological Effects Branch regarding the potential for impacts to terrestrial and aquatic species effects and the Health Effects Division regarding the potential impacts to human health.

If a concern is raised, SRRD, RD, HED, PSPS, and BEAD will be notified. EFED will work with SRRD or RD to scope out the ground-water evaluation to insure that the assessment will provide the information needed to make a regulatory decision. If further analysis is needed, it will be scheduled. BEAD will begin to prepare usage information.

Step 4 - Ground-water evaluation. (Timeframe - 1 to 4 months)

EFED conducts the ground-water evaluation as determined in step 3. EFED evaluates ground-water monitoring data and determines if a ground-water monitoring study should be required.

On the basis of this evaluation of the various kinds of data that may indicate ground-water concerns, EFED in consultation with PSPS and the other relevant Divisions will suggest risk mitigation measures, such as ground-water advisory statements or use limitations, that are appropriate to the degree and specificity of the potential contamination. In the case of data indicating that the pesticide meets or exceeds the specific criteria[9] for consideration of restricted use classification,

---

[9] These criteria will be promulgated as 40 CFR §152.170(b)(3).

EFED will consult with PSPS regarding the commencement of regulatory action (Notice of Proposed Rulemaking).

If appropriate, EFED will identify potential mitigation steps and provide a qualitative evaluation of effectiveness.

Step 5 - Notify lead division of the concern for ground-water contamination and forward usage information. (Timeframe - 1 to 2 weeks)

If a concern is raised regarding the impacts from ground-water contamination, SRRD or RD will be notified. EFED will indicate whether the chemical meets or exceeds the criteria for regulatory action and recommend potential mitigation steps. BEAD completes and forwards their usage information to SRRD, RD, and EFED.

Step 6 - Notify registrant of ground-water concern and identify the regulatory criteria that have been exceeded. (Timeframe - 4 weeks for steps 6 and 7)

This is a notification step. SRRD or RD notifies affected registrant(s) that OPP is concerned about the pesticide's potential to contaminate ground water and that OPP is considering regulatory action. Documentation from the ground-water evaluation will be sent as well. The registrant will be encouraged to propose risk mitigation measures.

Step 7 - Identify cost and applicability of mitigation measures, prepare preliminary benefits assessment, and develop strategy for negotiation.

To prepare for the negotiations, BEAD will evaluate the mitigation measures on a nationwide and local basis and develop quick cost analysis. BEAD also will perform a preliminary benefits assessment and will identify alternatives. In addition, OPP will develop strategy for negotiation and will consider potential mitigation measures and monitoring requirements.

Step 8 - Negotiation. (Timeframe - 4 weeks)

SRRD or RD will hold a meeting with the registrants and discuss potential mitigation measures and monitoring requirements. RD or SRRD also may solicit input from state and EPA Regional Offices, and in some cases may hold a public meeting. OPP anticipates, however, that this will not occur routinely. In those cases when a public meeting is held, OPP anticipates that the 9 month timeframe may be exceeded.

In either case, the timeframe for step 9 will be determined during this step.

Step 9 - Evaluate final registrant proposal and make risk/benefit determination with respect to ground-water contamination. (Timeframe - 4 to 12 weeks)

During the final step in the process, the registrant proposal is evaluated. Mitigation, monitoring data, and the relative potential of the alternatives to contaminate ground water are considered. This step also includes weighing risks and benefits and determining whether to accept or reject the registrant proposal. This step, as well as the process, ends by making a regulatory decision and by requiring monitoring data, if needed.

V. Clarification of Task Force Results

Since the new paradigm was developed, several general questions arose that warranted clarification. These questions are described in this section along with a response.

A. Ecological effects

1. Applicability of new paradigm to registration and special review.

One question that arose was the applicability of the new paradigm to the registration program and to special reviews. The policy was clear in its focus on reregistration. In contrast, it was not clear how registration and special review were considered during the course of developing the new paradigm. This is of concern because registration, reregistration, and special reviews are different regulatory processes. Reregistration operates under Congressionally-mandated deadlines, while registration and special reviews do not. Also, the information that may be available for a pesticide that has been in use for some time may be quite different than that for a new pesticide being considered for registration. For example, incident data, which was highlighted to be an important part of risk characterization in the new paradigm, may be available for old pesticides, but not for new.

Concern also was raised because of the de-emphasis on field studies, and the impact on ecological risk assessment. Since field studies will generally not be required to determine ecological effects, pesticides could be registered without any field data. Therefore, certain routes of exposure such as dermal and inhalation, indirect effects such as reduced food availability, and ecosystem effects will not be considered.

Response: It is important to revisit the overriding emphasis of the policy. That is, risk managers should only ask for a study when the information from such a study will improve our ability to make decisions. Applied to the registration program,

this means that if OPP has significant uncertainty about the effects of a new chemical in the field which cannot be resolved with out a field study, then a field study should be considered. However, before requiring such a study (or any other study) OPP should know what actions to take. This relates to knowing how to use the results of a study before requiring it.

2. Regulatory decisions in the absence of avian field studies.

A question also was raised regarding the statement "The AA agrees with workgroup conclusion that the avian field study provides very limited new information to an avian risk assessment, and that such field studies confirm the results of the lab studies" (Ref. 4). Commenters have asked to be shown the scientific basis for this statement.

Concern also was raised regarding the conditions under which a field study would be required. The Task Force indicated that field studies could be required under unusual circumstances, yet did not make it clear what these "unusual circumstances" would be.

Response: The Task Force conclusion that the avian field study provides very limited new information to an avian risk assessment and thus would only be required under unusual circumstances was based to a large degree upon two factors. First, a consensus of Task Force members indicated that the results of the avian field studies reviewed by OPP always confirmed predictions of adverse effects, primarily bird mortality, based upon lower tiered studies. Second, a preliminary analysis of "in-house" avian field studies supported this conclusion. The Task Force recognized that the conclusion was based upon limited data on organophosphate and carbamate pesticides. Thus, the "unusual circumstances" where avian field studies may be required in the future could include new pesticides which exceed the LOCs for birds and which have chemistry and mode of actions significantly different from organophosphate and carbamate pesticides. However, other cases may arise which also may warrant the requirement of a field study.

3. New LOCs were identified.

Commenters also indicated that two new LOCs are identified by the new paradigm. This was questioned because scientific justification was not provided and the LOCs have not undergone adequate analysis. Specifically, the LOCs are (1) LD_{50}/sq ft > 1/2 and (2) EEC > 1/2 LC_{50}.

Response: The new LOCs are based on the results of a preliminary, retrospective analysis of 20 field studies. The

results support the conclusion that bird kills in the field may occur at these LOCs.

Also, the LOCs for ecological effects have been established based on Agency regulations and guidance[10]. In 1975, a Rebuttable Presumption Against Registration (RPAR, the predecessor to Special Review), could be initiated when the estimated environmental exposure was equal to or greater than one-half the acute toxicity value for aquatic organisms. The "trigger" for birds at that time was equal to the acute avian toxicity value with no "safety factor". Internally, OPP always believed that some safety factor was needed, but the majority of pesticides for which avian field studies were required had estimated exposures much greater than the acute toxicity values for birds. Thus, OPP never established a number that captured the notion of "approaching" the bird toxicity value.

In the recent proposed revision to Part 158, OPP stated that the avian field study would be required when the estimated environmental exposure is equal to or greater than one-half the acute avian toxicity value. This is identical to the trigger for the aquatic mesocosm.

4. Other LOCs.

A question also was raised regarding endangered species and mammals, whether they are endangered or not. The new paradigm did not specifically address the use of the existing LOCs for endangered species and mammals or identify new LOCs. It is not clear how these endpoints of concern will be addressed by the new paradigm.

Response: The LOCs for endangered species (Ref.3) are unaffected by the new paradigm. While not specifically addressed in the findings of the Task Force (Ref. 4), the LOCs for wild mammals will be identical to those for birds.

B. Ground water

1. Ability to meet the protective and timely goals of the new paradigm.

A question was raised whether or not making decisions more quickly could lead to less protective decisions for ground water.

---

[10] Examples include the regulations for Registration, Reregistration and Classification (40 FR 28242); the current regulations (40 CFR 154.7); the criteria for initiation of Special Review (40 CFR 154); Criteria for Restriction for Use by Certified Applicators [40 CFR 152.170(c)]; 1988 Guidance Document for Conducting Terrestrial Field Studies (Ref. 3)

Although the intent of the new paradigm is to make more protective and timely decisions, it may be difficult because of the uncertainty associated with ground-water monitoring data and computer modeling results if field data from appropriately designed and conducted field studies are not available.

Response: The Task Force emphasizes that OPP needs to make decisions that "result in a significant and prompt improvement in environmental quality. More decisions--environmentally protective decisions, with a major focus on remediation, where appropriate-- will be made with far greater speed under the new paradigm [...]". If the existing database is inadequate to support decisions that would be protective, and that database can be improved by requirement of a ground-water field study, the decision to require such a field study should be made at an earlier stage in the registration and reregistration processes. Also, if the effectiveness of specific remediation options cannot be confirmed, monitoring should be required to ensure that the Agency is acting in a more protective mode by requiring them.

The Task Force recognized the value of the information provided by the ground-water field studies. These studies are designed to gather data to support registration and reregistration decisions. If the alternative to requiring a ground-water field study is that the Agency is compelled to make decisions that are less protective, even though these decisions are made more rapidly, this was clearly not the intended outcome of the new paradigm.

As a consequence, it is essential for OPP to closely monitor the implementation of the new paradigm. First, OPP will track the process to ensure that the timeframes and steps outlined in sections IV and V are followed. Second, it will include evaluating the results of the process. If the decisions that result are not made in a timely manner and are not protective, then OPP will need to step back and re-evaluate the implementation plan. This will be true for ground-water as well as for ecological effects.

VI. Conclusions and Long-term Research and risk Assessment Improvement Goals

OPP believes that the implementation plan described in this paper will help to improve OPP's ability to meet the reregistration deadlines that have been established and to evaluate registration actions in a more timely manner. The resulting decisions will achieve the Task Force goals by being environmentally protective and more timely. OPP believes it is taking a step in the direction of environmental protection by its emphasis on early decision-making and risk mitigation.

To provide continued scientific support for the new paradigm, OPP has identified several areas which could benefit from additional research. In some cases, work has already begun.

A. Ecological effects

The following project has already begun and a report should be completed by spring of 1994:

- Retrospective Analysis of Terrestrial Field Studies

  A synopsis of all "in-house" terrestrial field studies will be done by the EPA's Office of Research and Development"s Environmental Research Laboratory in Corvalis, Oregon. The results will be summarized and analyzed to verify the preliminary analysis of 20 field studies and to determine if terrestrial field studies validate OPP's presumption of terrestrial risk.

Additional projects are planned to begin in October 1993, and reports should be available by the end of 1994. Some projects may continue beyond 1994 as the need for additional work becomes apparent:

- Retrospective Analysis of Aquatic Field Studies

  A synopsis of all completed mesocosms and pond studies will be done by ORD's Environmental Research Laboratory at Duluth, Minnesota. The results will be summarized and analyzed to determine if they validate the presumption of aquatic risk.

- Risk Mitigation and Monitoring Guidance Projects

  In response to the Task Force emphasis on risk mitigation, this project will identify and advance risk reduction and mitigation measures for terrestrial organisms and their habitats threatened by pesticide use.

  In addition, terrestrial effects monitoring guidance will be developed as a tool to measure the effectiveness of risk mitigation measures. Guidance should include residue and effects on terrestrial non-target organisms. The guidance may be tiered and should provide site-specific guidance.

  Two other projects will look into risk reduction and mitigation measures as well. One project will focus on aquatic organisms and their habitats threatened by pesticide use and the other on nontarget plants. Monitoring guidance also will be developed.

- Wildlife Utilization Project

  The Task Force emphasized the development of additional tools to further characterize the risk of pesticide use to wildlife, including the exposure of wildlife to pesticide residues. This project provides for the development of a computerized (e.g., dBase III+) database using Gusey and Maturgo (1973) wildlife utilization data. Data would be used by scientists to better characterize terrestrial exposure and risk. The data would serve as a starting point for the development of a wildlife utilization model. Additional literature and survey information would eventually be incorporated into the data base.

- Evaluation of Aquatic Habitat Project

  The Task Force emphasized the need for additional tools to characterize the exposure and risk of pesticides to aquatic organisms. These tools may be available from groups in other parts of the Agency or outside the Agency.

  This project will coordinate the search for existing databases and maps for characterizing aquatic organism exposure and risk from pesticides use. High value use areas for aquatic organisms, such as areas adjacent to productive streams/rivers, marshes, as well as critical habitats for endangered and threatened species, will be identified.

  This project also involves participation on Agency Habitat and Biodiversity workgroups.

- Evaluation of Terrestrial Habitat Project

  This project will coordinate the search for existing databases and maps for characterizing wildlife exposure and risk from pesticides use. High value use areas for wildlife, such as areas adjacent to wildlife refuges, bird migratory flyways, critical habitat for endangered and threatened species, will be identified.

- Incident Data Project

  This project is a continuation and enhancement of the "Ecological Incident Information System" and involves entering incident data on pesticides and other toxic chemicals. Data sources include OPP files, the states, and other federal agencies such as the U.S. Fish and Wildlife Service. Currently, 200 incident records have been evaluated and entered.

  The goal of this project is to provide the Agency scientists, registrants, the Regions, the states, and

outside scientists with a file structure so that ecological effects data can be easily accessed and used to characterize ecological risk assessments.

- EEB One-Liners/Chesapeake Bay Project

  This project is a continuation and enhancement of current computerized Ecological Effects Branch's (EEB) "One-liner" files and includes all pesticides for which eco-toxicity exists in EEB files. Currently, EEB has approximately 4400 records for 209 chemicals. Additional data files need to be entered, and the data base needs to be updated and verified.

  The goal of this project is to provide the Chesapeake Bay Project, OPP scientists, registrants, the Regions, the states, and outside scientists with a file structure so that ecological effects data can be easily accessed and used for ecological risk assessments.

- Value of [Additional] Information Project

  Decisions to ask for higher tiered data to support registration of pesticides is clearly a risk management decision. Risk managers need to know what additional information higher tiered data will provide for risk assessment, and what value it will add to risk management decisions.

  Scientific rationale will be developed supporting decisions to require or not require tier 2, 3 and 4 data. Factors considered in the rationale will include: Tier 1 toxicity data, fate and transport characteristics, use pattern, LOCs, etc.

- Species Tested versus Species Exposed Project

  The Task Force considered an analysis of the species exposed versus the species tested as an essential piece of information in making regulatory decisions for ecological effects. Existing eco-toxicity databases will be identified and collected, and databases will be analyzed to compare the sensitivity of various species tested to pesticides. Lists of species identified (and likely exposed to pesticides) with different use patterns will be developed. Comparisons of species tested and species exposed will be made. Extrapolations from one species to another based on body weight and other factors will be considered.

- Eco-Effects Modelling Project

  A number of models exist or are currently being developed. In order to determine which, if any of these models will assist in characterizing ecological risk, this project will provide a review and evaluation of eco-effects computer models such as FGETS, RAMAS, PIRANHA and LERAM, etc. Hopefully, one or more of these models will be useful to predict and/or characterize adverse effects in non-target organisms, their populations and communities.

  The endpoints to be considered will include direct and indirect mortality, reproductive/chronic effects, bioaccumulation, age-structured population dynamic changes and bioenergetic ecosystem effects.

- Uncertainty in Ecological Risk Characterization Project

  Uncertainty exists in every step of ecological risk characterization, which includes identification of endpoints of concern, effects and exposure characterization, quotient calculations, refinement of quotient estimates, modelling, etc. Identifying the uncertainty associated with this information will place it in perspective and may lead to better regulatory decisions.

  Existing eco-toxicity, exposure, and risk data bases will be analyzed for variability. Best approaches and statistical techniques will be selected with statistical assistance. Based upon these analyses and existing analyses from the literature, statements of uncertainty will be developed for use in ecological risk assessments.

B. Ground water

- Tools must be developed and refined to enhance OPP's modeling and GIS capabilities. In particular, model validation and enhancement of pesticide leaching and runoff models will greatly improve OPP's ability to rapidly respond to questions about the impact of new uses of pesticides or continued use of pesticides on ground and surface water quality. Currently, there are uncertainties about the predictive value of these models. Significantly more research and field work is needed before these questions are resolved.

- The emphasis of the new paradigm on risk mitigation is very clear. What remains to be established is the overall impact of individual risk mitigation measures on environmental quality. These effects should be quantified by requirement of monitoring to (1) determine the impact of each measure on changing the quality of ground water, surface water, air,

and the ecosystem, and (2) to establish an integrated approach to resource assessment to ensure that benefits to one environmental medium that result from individual mitigation measures are not offset by significant costs incurred by others.

VII. References

1. Kenaga, E.E. 1973. Factors to be Considered in the Evaluation of the Toxicity of Pesticides to Birds in Their Environment. Environmental Quality and Safety. Academic Press, N.Y. II:166-181.

2. U.S. Environmental Protection Agency. 1986. Standard Evaluation Procedure for Ecological Risk Assessment. EPA 540-9-86-167.

3. U.S. Environmental Protection Agency. 1988. Guidance Document for Conducting Terrestrial Field studies. EPA 540/09-88-109.

4. U.S. Environmental Protection Agency. 1992. Memorandum from Linda J. Fisher, Assistant Administrator, to Douglas Campt, Director, Office of Pesticide Programs, dated October 29, 1992. SUBJECT: Decisions on the Ecological, Fate, and Effects Task Force.